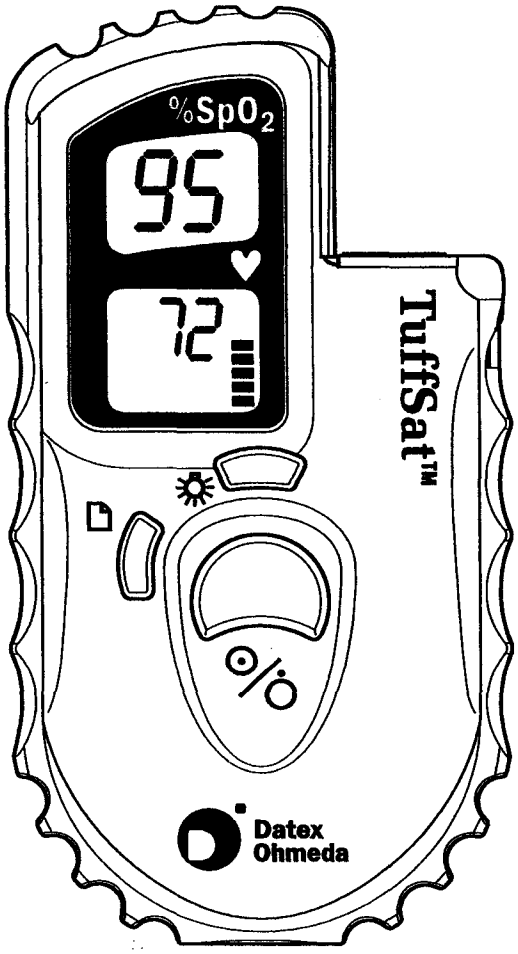
Datex-Ohmeda

TuffSat™ Pulse Oximeter

User's Guide and Service Manual



The instructions for using this device are in English.
In Norway, this device is to be used *only* by qualified medical professionals.
Instruksjoner for bruk av denne enheten er på engelsk.
I Norge skal denne enheten kun benyttes av kvalifisert medisinsk personell.

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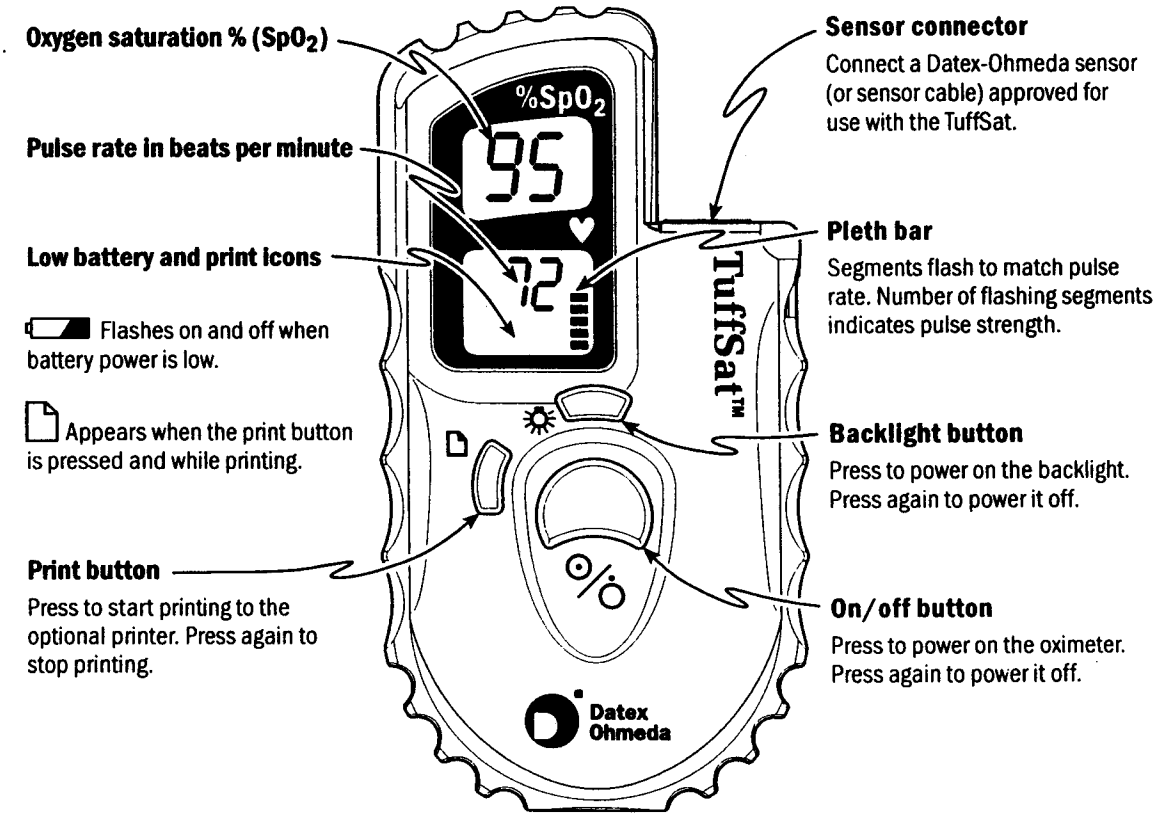
Oxygen saturation % (SpO_2)
Pulse rate in beats per minute
Low battery and print icons
Flashes on and off when battery power is low.
Appears when the print button is pressed and while printing.
Print button
Press to start printing to the optional printer. Press again to stop printing.
Sensor connector
Connect a Datex-Ohmeda sensor (or sensor cable) approved for use with the TuffSat.
Pleth bar
Segments flash to match pulse rate. Number of flashing segments indicates pulse strength.
Backlight button
Press to power on the backlight. Press again to power it off.
On/off button
Press to power on the oximeter. Press again to power it off.
%SpO2
95
72
TuffSat™
Datex Ohmeda

Important

This manual is subject to periodic review, update, and revision. Customers are cautioned to verify that the information in this manual applies to the software and hardware present in the equipment.

Attention! Consult the accompanying instructions before using this device.

This device performs as described in this manual, and in accompanying labels and inserts, when assembled, operated, maintained, and repaired in accordance with the instructions provided.

This device must be cleaned and checked periodically. Do not use a defective device. Parts that are broken, missing, plainly worn, distorted, or contaminated should be replaced immediately. If repair or replacement becomes necessary, request service advice from Datex-Ohmeda (information is listed on the back cover). Do not repair this device or any of its parts other than in accordance with written instructions provided by Datex-Ohmeda.

The user of this device shall have the sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, unauthorized service, damage, or alteration by anyone other than Datex-Ohmeda.

The safety, reliability, and performance of this device can be assured only under the following conditions:

- If it is used according to the accompanying operating instructions.
- If fittings, extensions, changes, or repairs are carried out by agents authorized by Datex-Ohmeda.

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Table of Contents

1/Overview

Product description **1-1**
Clinical use 1-1
TruTrak™ data sampling system 1-2
Theory of operation **1-2**
Signal processing 1-2
Calibration 1-4
Assumptions 1-4
Methods 1-4
Circuit board 1-5
Patient and operator safety **1-6**
General 1-6
Electrical shock and flammability hazard 1-6
Fire/explosion hazard 1-6
Failure of operation 1-6
Data validity 1-6
Operator safety 1-6
Patient safety and operator safety 1-6
Patient safety (oximeter) 1-7
Patient safety (sensors) 1-7
Cleaning 1-7
Maintenance and repair 1-8
Disposal 1-8

2/Oximeter Features and Use

Product information labels 2-1
Oximeter features and controls **2-2**
Top view 2-3
Checking normal operation **2-3**
Using the oximeter **2-4**
Data validity and signal strength **2-5**
Pleth bar (pulse rate and strength indicator) 2-5

3/Maintenance, Troubleshooting, and Service

Oximeter maintenance **3-1**
Replacing oximeter batteries 3-1
Cleaning the oximeter 3-2
Sensors 3-2
Troubleshooting **3-2**
Service policy **3-4**
Ordering parts and obtaining service 3-4
Packaging and returning equipment 3-4
Repair procedures **3-5**
Disassembling the oximeter 3-5
Replacing parts 3-6
Assembling the oximeter 3-6
Assembly drawing **3-7**
Parts list **3-8**

Table of Contents

4/Compliance and Specifications

Electromagnetic compatibility (EMC) **4-1**
- Electromagnetic effects 4-1
- EMC performance 4-1

Compliance with standards **4-2**
- General safety requirements 4-2
- Requirements for pulse oximeters 4-2
- Software safety checks 4-2

Performance specifications **4-3**
- General 4-3
- SpO_2 4-3
  - Interfering substances 4-3
- Sensor emitter wavelength ranges 4-3
- Pulse rate 4-3
- Alarms 4-3
- Displays 4-4
  - Updates 4-4
  - Visibility 4-4
- Power 4-4
  - Low battery indicator (screen icon) 4-4
- Environment 4-4
- Dimensions and weight 4-4

Appendix: Printer Features and Use

Functions and features **A-1**
- How the TuffSat stores data A-1
- Printer components A-2

Using the printer **A-2**
- Powering the printer A-2
- Positioning the oximeter and printer A-3
- Printing data A-3

Sample printouts **A-4**
- Real-time printout *and* Trend #1 printout A-4
- Trend #2 printout A-5

Troubleshooting **A-5**

Printer maintenance **A-6**
- Replacing printer paper A-6
- Cleaning the printer A-7

Ordering the printer and printer accessories **A-7**

Printer specifications **A-8**
- Electromagnetic compatibility (EMC) A-8
- Print indicator (screen icon) A-8
- Power A-8
- Environment A-8
- Dimensions A-8

Warranty

1/Overview

This chapter contains:

- A brief description of the Datex-Ohmeda TuffSat™ Pulse Oximeter.
- The theory of operation for the oximeter.
- A list of the precautions you must take when using this device.

Product description

The TuffSat oximeter is a small, durable, portable pulse oximeter that operates on battery power. These items are included with the oximeter:

- This manual, which includes an insert that lists the sensors you can use with the oximeter.
- Four 1.5V alkaline AA batteries.
- Neoprene carrying case with belt clip.

The TuffSat oximeter is capable of printing data through an infrared link to the optional Hewlett-Packard® Infrared Printer (HP 82240B). For information on ordering and using this printer with the TuffSat oximeter, see the Appendix: *Printer Features and Use.*

Clinical use

The TuffSat oximeter is designed specifically for spot-checking arterial oxygen saturation (SpO_2) and pulse rate. This easy-to-use oximeter is ideal for use in the environments listed below:

- Respiratory care
- Subcritical care for hospital satellite locations
- Home care
- Prehospital/EMS
- Rehabilitation
- Physician's office

WARNING: Patient safety. The TuffSat oximeter is *not* intended for continuous monitoring. It has no alarms (audible or visual) and no user-definable parameters.

TruTrak™ data sampling system

The TruTrak data sampling system, patented by Datex-Ohmeda, enables the TuffSat oximeter to calculate SpO_2 many times each second through advanced statistical data processing. While other oximeters calculate only at the peak and trough of each waveform, the TuffSat assesses SpO_2 continuously. The TruTrak data sampling system provides reliable readings during times of low perfusion, motion, or electrical interference.

The TuffSat oximeter employs an analog/digital (A/D) converter and maximized digital signal processing techniques to produce samples for the TruTrak system to process. The result is a highly reliable level of oximetry performance.

Theory of operation

The TuffSat oximeter uses a two-wavelength pulsatile system—red and infrared light—to distinguish between oxygenated (O_2Hb) and reduced (HHb) hemoglobin, each of which absorbs different amounts of light emitted from the oximeter sensor. The SpO_2 and pulse rate are determined by the oximeter through sensor signal processing and microprocessor calculations.

Signal processing

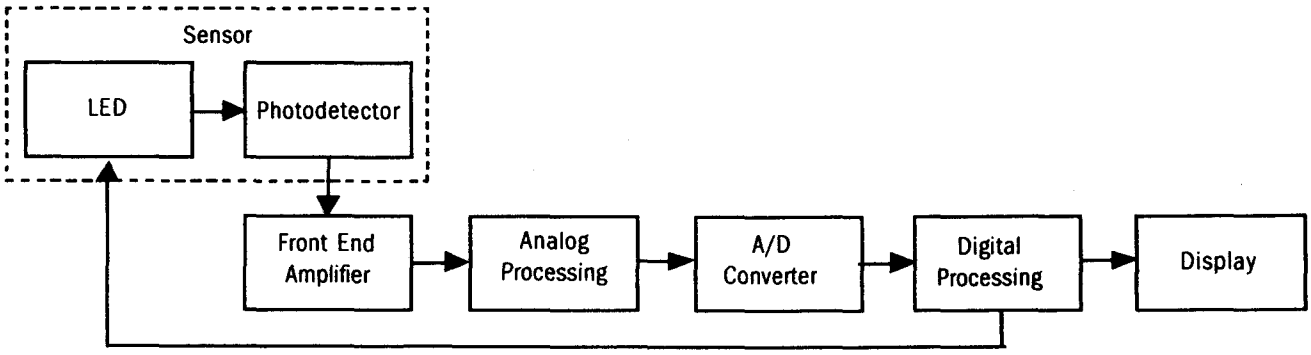


Figure 1-1. Signal processing block diagram

The sensor contains a light source and a photodetector:

- The light source consists of red and infrared light-emitting diodes (LEDs).
- The photodetector is an electronic device that produces an electrical current proportional to incident light intensity.

The two light wavelengths generated by the sensor light source (the red and infrared LEDs) pass through the tissue at the sensor site. The light is partially absorbed and modulated as it passes through the tissue.

Arterial blood pulsation at the sensor site modulates transmission of the sensor's light. Since other fluids and tissues present generally don't pulsate, they don't modulate the light passing through that location. The pulsatile portion of the incoming signal is used to detect and isolate the attenuation of light energy due to arterial blood flow.

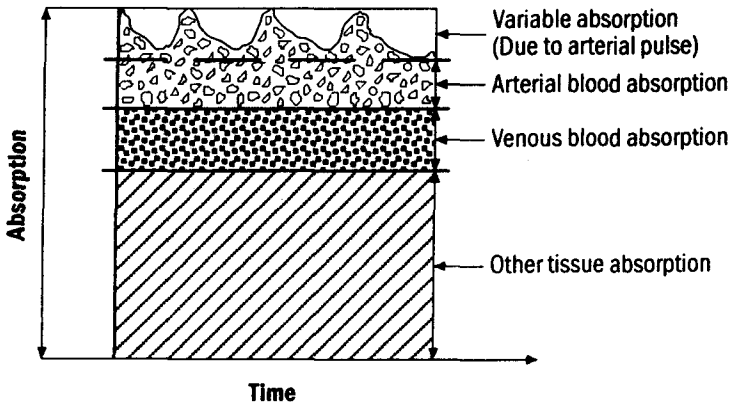


Figure 1-2. Comparative light absorption

The sensor's photodetector collects and converts the light into an electronic signal. Since O_2Hb and HHb allow different amounts of light to reach the photodetector at the selected wavelengths, the electronic signal varies according to which light source is "on" (red or infrared) and the oxygenation of the arterial hemoglobin. The oximeter uses this information to calculate the relative percentage of O_2Hb and HHb.

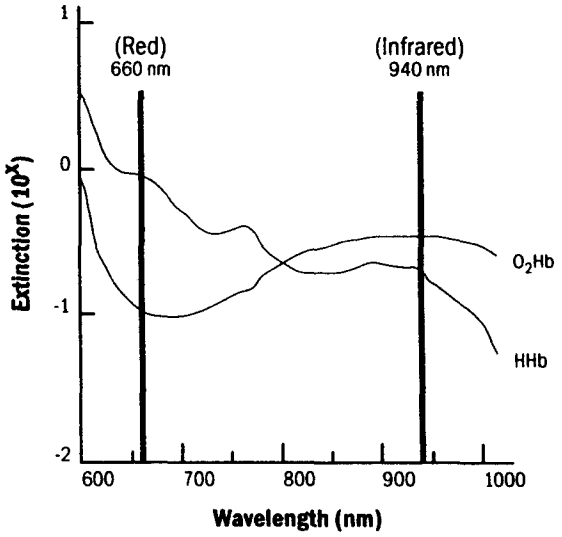


Figure 1-3. Extinction vs. wavelength graph

The photodetector sends the electronic signal, which contains the light intensity information, to the oximeter. The oximeter's electronic circuitry processes the electronic signal, calculates the SpO_2 and pulse rate values, and displays them on the screen.

Calibration

Datex-Ohmeda pulse oximeters use two wavelength ranges, 650 nm to 665 nm and 930 nm to 950 nm, both with an average power of less than 1 mW. These wavelengths are used to calculate the presence of oxyhemoglobin (O_2Hb) and reduced hemoglobin (HHb).

A CO-oximeter typically uses four or more wavelengths of light and calculates reduced hemoglobin (HHb), oxyhemoglobin (O_2Hb), carboxyhemoglobin (COHb), and methemoglobin (MetHb).

Therefore, pulse oximetry readings and CO-oximetry readings will differ in situations where a patient's COHb or MetHb are increased. Increased patient COHb leads to falsely increased SpO_2 in all pulse oximeters.

Assumptions

The calculation of SpO_2 assumes 1.6% carboxyhemoglobin (COHb), 0.4% methemoglobin (MetHb), and no other pigments. These values are based on the Datex-Ohmeda Pulse Oximeter Empirical Calibration Study. Appreciable variation from these values will influence SpO_2 accuracy.

Methods

Two different methods of calibration are currently used by manufacturers of pulse oximeters: *fractional* and *functional.*

Important: The TuffSat pulse oximeter uses the functional calibration method. The user cannot change the calibration method to fractional.

- *Fractional* saturation is represented mathematically as the percentage of the total amount of hemoglobin carrying oxygen. It is determined by dividing the oxyhemoglobin by the total hemoglobin.

$$\text{Fractional } SpO_2 = \left(\frac{O_2Hb}{Hb_{TOTAL}}\right) \times 100 = \left(\frac{O_2Hb}{O_2Hb + HHb + COHb + MetHb}\right) \times 100$$

- *Functional* saturation is represented mathematically as the percentage of hemoglobin capable of carrying oxygen that is carrying oxygen.

$$\text{Functional } SpO_2 = \left(\frac{O_2Hb}{Hb_{TOTAL} - COHb - MetHb}\right) \times 100 = \left(\frac{O_2Hb}{O_2Hb + HHb}\right) \times 100$$

The functional calibration is obtained by multiplying the fractional SpO_2 by a value of 1.02.

Circuit board

The circuit board contains all the circuitry for the TuffSat oximeter. The functions performed by this board are illustrated below.

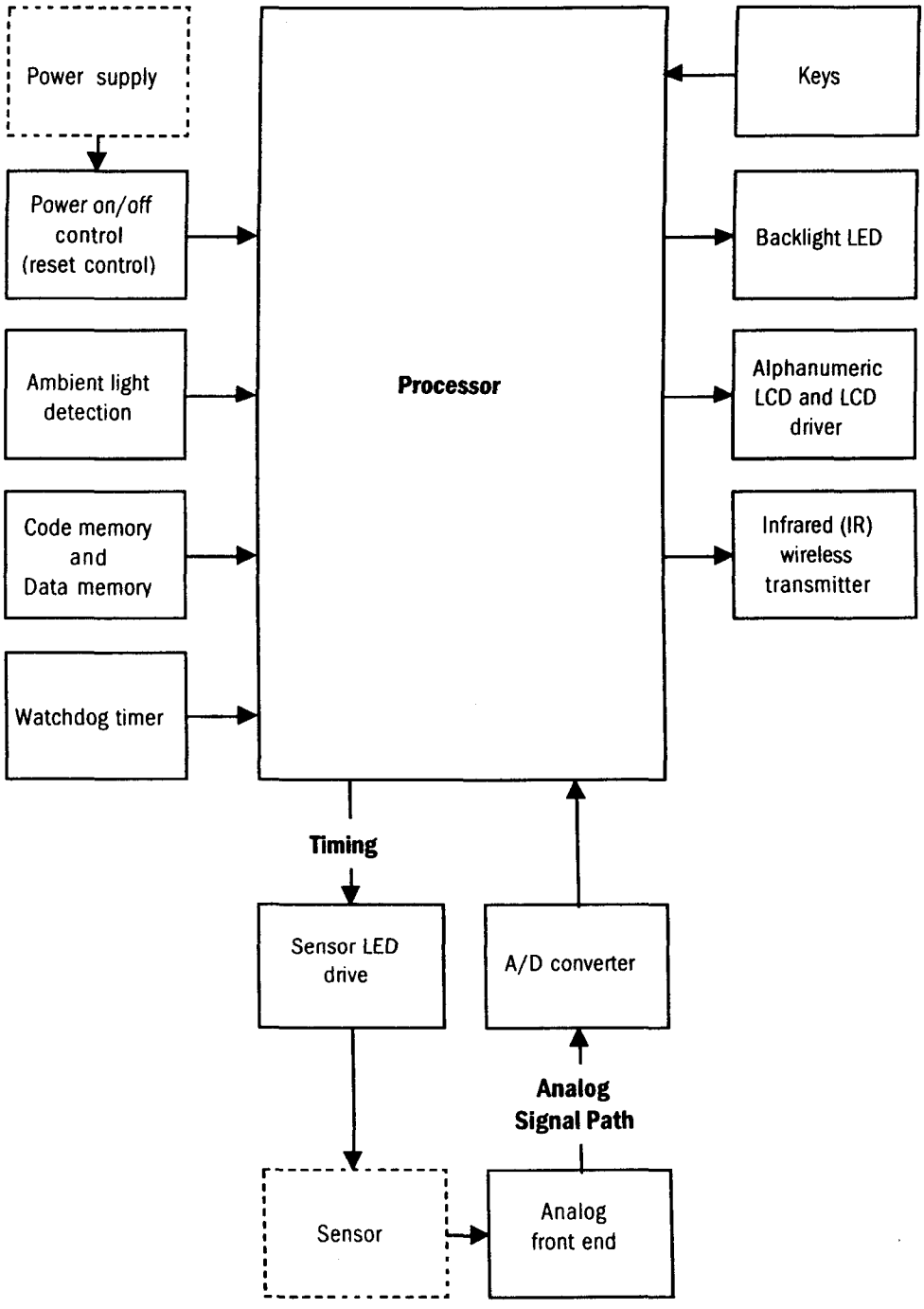


Figure 1-4. Circuit board block diagram

Patient and operator safety

Warnings and cautions associated with following safe practices while using the oximeter appear throughout this manual.

- **WARNINGS** indicate potentially harmful situations that may cause injury to a patient or operator.
- **CAUTIONS** indicate conditions that may lead to equipment damage or malfunction.

Read this section carefully before using the oximeter to monitor patients.

General

Caution: U.S. Federal and Canadian laws restrict this device to sale by or on the order of a licensed medical practitioner.

Electrical shock and flammability hazard

Warning: Power off the oximeter before cleaning or servicing.

Fire/explosion hazard

Warning: Do not use the oximeter in the presence of a flammable anesthetic mixture with air, or with oxygen or nitrous oxide.

Warning: Use only AA batteries in the oximeter.

Failure of operation

Warning: It is possible for any device to malfunction; therefore, always verify unusual data by performing a formal patient assessment.

Warning: Do not use the oximeter if it fails to function as described or if the validity of data is questionable. Refer to the appropriate sections of this manual to identify and correct the malfunction.

Data validity

Warning: To prevent erroneous readings, do not use an inflated blood pressure cuff or arterial blood pressure measurement device on the same limb as the oximeter sensor.

Warning: Interfering substances, excessive ambient light, excessive motion, low perfusion, low signal strength, incorrect sensor placement, or electrical interference at the sensor site can result in the display of inaccurate SpO_2 data.

Operator safety

Warning: Do not handle hot or leaking batteries.

Patient safety and operator safety

Warning: To protect against injury and equipment damage from leaking batteries, remove the batteries when the oximeter is not to be used for some time.

Patient safety (oximeter)

Warning: The TuffSat oximeter is not intended for continuous monitoring. It has no alarms (audible or visual) and no user-definable parameters.

Warning: Never test or perform maintenance on the oximeter while using it to monitor a patient.

Warning: When the battery becomes depleted, the oximeter shuts off. No alarm sounds.

Warning: The correct use of the oximeter is to measure only arterial oxygen saturation (SpO_2) and pulse rate. A pulse oximeter does not measure respiration and should never be used as a substitute for an apnea monitor.

Warning: This device is not intended for use in a magnetic resonance imaging (MRI) environment.

Patient safety (sensors)

Warning: When the display indicates an error condition or the oximeter appears to be operating abnormally, disconnect the sensor immediately.

Warning: Prolonged monitoring or patient condition may require you to periodically change the sensor site. If there is evidence of blistering, skin erosion, or ischemic skin necrosis (such as skin discoloration or reddening), change the site immediately. Otherwise, change the site as specified in the instructions for the sensor.

Warning: Discard a damaged sensor immediately. Do not repair a damaged sensor or use a sensor repaired by others.

Warning: To prevent patient injury or equipment damage, use only Datex-Ohmeda sensors approved for use with this oximeter. For complete information about the safe and appropriate use of a sensor, consult the instructions for that sensor.

Cleaning

Caution: Follow these guidelines when cleaning the oximeter:

- Do not autoclave, pressure sterilize, or gas sterilize the oximeter.
- Use cleaning solution sparingly. Do not immerse the oximeter in liquid. Excessive solution can flow into the oximeter and damage internal components.
- When cleaning the display lens, do not use abrasive cleaning compounds or other materials that could damage the lens.
- Do not use petroleum-based solutions or solutions containing acetone, freon, or harsh solvents. These substances may damage the oximeter and cause a malfunction.

Caution: Disposable sensors are intended for single-patient-use only.

Maintenance and repair

Caution: An operator may perform only maintenance procedures specifically described in this manual. Refer servicing to qualified service personnel who are trained in the repair of this equipment.

Caution: Internal electronic components are susceptible to damage by electrostatic discharge. To avoid damage when disassembling the oximeter, observe the standard precautions and procedures for handling static-sensitive components.

Disposal

Caution: When the oximeter has reached the end of its useful life, dispose of it in accordance with local procedures and regulations.

2/Oximeter Features and Use

This chapter contains:

- Descriptions of the product information labels that appear on the oximeter.
- Descriptions of the oximeter's features and controls.
- Instructions for checking the operation of the oximeter.
- Instructions for using the oximeter.
- Information to help you determine the validity of the SpO_2 and pulse rate values you see on the oximeter.

Product information labels

Labels on the TuffSat oximeter provide product information. Agency and regulatory symbols are described in chapter 4.

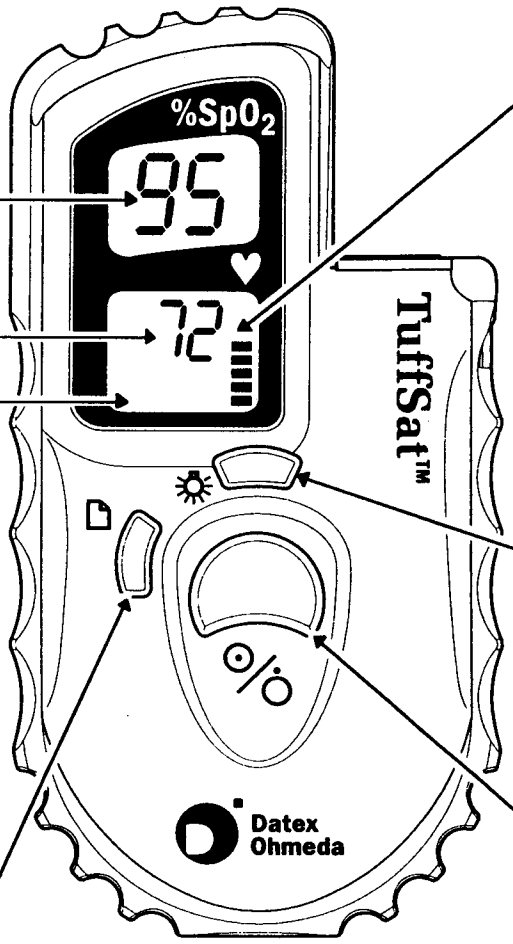
Not for continuous monitoring. The TuffSat has no alarms (audible or visual). It is to be used only for spot-checking SpO_2 and pulse rate.

SN Identifies the serial number for this product in the form: AAAYxxxxx.

The first three letters are specific to the product. The fourth letter indicates the year of manufacture (B = 1998, C = 1999, and so on. "I" and "O" are not used). The last five digits are the sequential number for the unit manufactured in the indicated year.

Ⓖ Identifies the warranty expiration date for this product.

Oximeter features and controls



Oxygen saturation % (SpO_2)

Pulse rate in beats per minute

Low battery and print icons

Flashes on and off until the batteries are replaced or until no power remains.

Indicates the battery power is low (10 to 60 minutes for alkaline batteries; not predictable for other battery types).

For more information, see *Power* in chapter 4.

Appears when the print button is pressed to start printing to the optional printer.

Pleth bar

The segments pulsate (flash on and off) to match the pulse rate. The number (or height) of lighted segments indicates the pulse strength.

For more information, see *Data validity and signal strength* later in this chapter.

Backlight button

Press to power on the backlight. Press again to power it off.

On/off button

Press to power on the oximeter. Press again to power it off.

When you stop monitoring, the power is switched off after 5 minutes to conserve battery power.

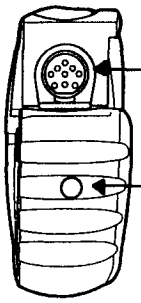
All patient data are erased from memory when the oximeter is powered off.

Print button

Press to start printing to the optional printer. Press again to stop printing.

For details about printing data, see the Appendix: *Printer Features and Use.*

Top view



Sensor connector

Receptacle for connecting a Datex-Ohmeda sensor (refer to the instructions for the sensor).

Infrared (IR) transmitter port

Port through which real-time and trend data are transmitted from the oximeter to the optional printer.

Checking normal operation

Before monitoring a patient, always check that the oximeter is operating normally.

WARNING: Patient safety. Never test or perform maintenance on the oximeter while using it to monitor a patient.

WARNING: Failure of operation.

- **Do not use the oximeter if it fails to function as described or if the validity of data is questionable. Refer to the appropriate sections of this manual to identify and correct the malfunction.**
- **It is possible for any device to malfunction; therefore, always verify unusual data by performing a formal patient assessment.**

1. Verify that the four AA batteries are installed. For installation instructions, refer to chapter 3.
2. Press the on/off button to power on the oximeter. As the oximeter completes its self-test, verify the following:
   - The backlight illuminates.
   - All display elements (including the printer and battery screen icons) illuminate briefly, then all turn off.
   - The backlight remains on until dashes (---) are displayed for the SpO_2 and pulse rate values.

   Note: If the low battery icon flashes on and off continuously, change the batteries as instructed in chapter 3.
3. Place a sensor on your finger and connect the sensor cable to the oximeter. When the SpO_2 and pulse rate values are displayed, verify that the lowest pleth bar segment remains on while one or more of the other segments flash on and off.
4. Disconnect the sensor cable from the oximeter. Verify that dashes are displayed in place of the SpO_2 and pulse rate values.
5. Reconnect the sensor cable to the oximeter. After SpO_2 and pulse rate values are displayed, remove the sensor from your finger and verify that dashes are displayed.

If the oximeter fails to function as described, refer to *Troubleshooting* in chapter 3.

Using the oximeter

WARNING: Patient safety.

- **This device is not intended for use in a magnetic resonance imaging (MRI) environment.**
- **To prevent patient injury or equipment damage, use only Datex-Ohmeda sensors approved for use with this oximeter. For complete information about the safe and appropriate use of a sensor, consult the instructions for that sensor.**

WARNING: Data validity. To prevent erroneous readings, do not use an inflated blood pressure cuff or arterial blood pressure measurement device on the same limb as the oximeter sensor.

1. Apply the sensor to the patient and connect it to the oximeter. Refer to the instructions for the sensor you are using.
2. Press the on/off button to power on the oximeter.

   After completing the brief self-test, the oximeter detects the SpO_2 and pulse rate values and monitoring begins.
3. Verify that the signal strength is adequate and that the data agree with your clinical evaluation of the patient. See *Data validity and signal strength* later in this chapter.

If the oximeter fails to function as described, refer to *Troubleshooting* in chapter 3.

WARNING: Patient safety.

- **When the display indicates an error condition or the oximeter appears to be operating abnormally, disconnect the sensor immediately.**
- **Prolonged monitoring or patient condition may require you to periodically change the sensor site. If there is evidence of blistering, skin erosion, or ischemic skin necrosis (such as skin discoloration or reddening), change the site immediately. Otherwise, change the site as specified in the instructions for the sensor.**
- **Discard a damaged sensor immediately. Do not repair a damaged sensor or use a sensor repaired by others.**
- **When the battery becomes depleted, the oximeter shuts off. No alarm sounds.**

WARNING: Data validity. Interfering substances, excessive ambient light, excessive motion, low perfusion, low signal strength, incorrect sensor placement, or electrical interference at the sensor site can result in the display of inaccurate SpO_2 data.

WARNING: Failure of operation. It is possible for any device to malfunction; therefore, always verify unusual data by performing a formal patient assessment.

Data validity and signal strength

The SpO_2 and pulse rate data are continuously calculated as a 12-second "moving" average. Both values are displayed when you begin to monitor a patient, however, their display may be delayed slightly for patients with lower pulse rates.

If the displayed pulse rate and the patient's palpated pulse rate vary significantly, motion artifact or other noise may be affecting the accuracy of the data. A cough or other hemodynamic pressure disturbance can also disrupt the pulse rate.

The stability of the SpO_2 readings is a good indicator of signal validity. Motion at the sensor site, low signal strength, incorrect sensor placement, and electrical interference may affect the stability of the readings.

To ensure the validity of the signal:

- Apply the sensor correctly to the patient (refer to the instructions for the sensor).
- Restrict motion at the sensor site or choose a site where motion is less likely.
- If possible, remove sources of electrical interference, such as electrosurgical and electrical/electronic devices.

Pleth bar (pulse rate and strength indicator)

The pleth bar—a column of eight segments—represents the plethysmographic waveform. During monitoring, the lowest segment is always on; the other segments pulsate (flash on and off).

- The rate at which the segments pulsate represents the pulse rate.
- The highest segment that pulsates represents the strength of the pulse—as the pulse strength increases, the number of pulsating segments increases.

If the pulse strength is low (only the lower four pleth bar segments pulsate), check for the following:

Poor alignment of sensor optical components
Make sure the sensor light source and sensor detector are directly opposite each other and that the detector is completely covered by the patient's skin. If the sensor site is thick, select a site where there is less distance between the light source and the detector.

Low perfusion
Change the sensor site or gently massage the site to increase perfusion.

Artificial fingernails or excessive fingernail polish
Select a different site or remove the artificial fingernails or polish.

3/Maintenance, Troubleshooting, and Service

This chapter contains:

- Maintenance instructions that include replacing the batteries and cleaning the oximeter.
- A chart for troubleshooting situations that may occur while using the oximeter.
- The Datex-Ohmeda service policy.
- Repair procedures that may be performed by qualified service personnel.
- An illustration of the oximeter to help you identify its parts and how it is assembled.
- A list of parts and their order numbers.

Oximeter maintenance

WARNING: Electrical shock and flammability hazard. Power off the oximeter before cleaning or servicing.

WARNING: Patient safety and operator safety. To protect against injury and equipment damage from leaking batteries, remove the batteries when the oximeter is not to be used for some time.

Replacing oximeter batteries

WARNING: Fire/explosion hazard. Use only AA batteries in the oximeter.

WARNING: Operator safety. Do not handle hot or leaking batteries.

1. Power off the oximeter.
2. Use a flat-blade screwdriver or coin to loosen the screw that secures the battery door to the back case of the oximeter. Remove the door.
3. Replace the depleted batteries with four new (or recharged) 1.5V AA batteries. Align the + on each battery with the + shown inside the battery compartment.
4. Position the battery door hinges in the slots on the back case. Close the door and tighten the screw that secures the door to the device.

Dispose of used batteries according to the manufacturer's instructions or your local regulations.

Cleaning the oximeter

CAUTION: Follow these guidelines when cleaning the oximeter:

- Do not autoclave, pressure sterilize, or gas sterilize the oximeter.
- Use cleaning solution sparingly. Do not immerse the oximeter in liquid. Excessive solution may flow into the oximeter and damage internal components.
- When cleaning the display lens, do not use abrasive cleaning compounds or any material that could damage the lens.
- Do not use petroleum-based solutions or solutions containing acetone, freon, or harsh solvents to clean the oximeter. These substances may damage the oximeter and cause a malfunction.

Cleaning agents

Mild soap and water	Cidex™ (2 vol% glutaraldehyde)
Quaternary ammonia	70 vol% isopropyl or ethyl alcohol
Water/bleach solution (100:1)	5 vol% sodium hypochlorite solution
Sporicidin (0.44 vol% phenol)	3 vol% hydrogen peroxide in water solution

1. Power off the oximeter.
2. Wipe the display lens with a cotton swab moistened with a cleaning agent.
3. Wipe the oximeter case with a soft cloth dampened with a cleaning agent. Do not allow excess liquid to enter the sensor connector.

Sensors

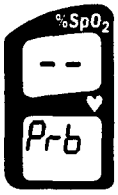
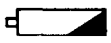
To clean a durable sensor, refer to the instructions for the sensor.

CAUTION: Disposable sensors are intended for single-patient-use only.

Troubleshooting

Error conditions activate messages that appear on the display. The following chart shows the messages that may appear and describes other conditions you may encounter while using the oximeter. Possible cause(s) and recommendations for responding to the message or for correcting the condition are provided.

Message or Condition	Cause	Recommendation
	If the display is blank and you are unable to turn on the backlight, the batteries are improperly installed, not installed, or dead.	Verify that fresh batteries are properly installed. If the condition persists, replace the circuit board.

Message or Condition	Cause	Recommendation
Backlight is on.	When the display is blank and the backlight is on, there has been a software failure.	Replace the circuit board.
	The sensor is not properly applied to the patient, or not connected to the oximeter. Loss of signal quality. Low perfusion, an electrosurgery device, excessive ambient light, or other interference was detected. Liquid in the oximeter sensor connector.	Attach the sensor as directed in the sensor instructions. Connect the sensor cable to the oximeter. Increase perfusion at sensor site or change site. Remove source(s) of signal interference. Disconnect the sensor and pour/shake the liquid out of the sensor connector.
	The sensor is not properly connected to the oximeter. Defective or incompatible sensor. Loose cable connection to the circuit board. Liquid in the oximeter sensor connector. Internal component malfunction.	Reconnect the sensor cable to the sensor connector on the oximeter. Replace the sensor. Use only Datex-Ohmeda sensors approved for use with the TuffSat™ pulse oximeter. Check the cable connection between the sensor connector assembly and the circuit board. Disconnect the sensor and pour/shake the liquid out of the sensor connector. Replace the sensor connector assembly. If the message reappears, replace the circuit board.
	The unit failed the power-on self-test and/or an internal component malfunctioned.	Power off, then on again. If the message reappears, replace the circuit board.
 Flashing on/off.	The battery power is low—10 to 60 minutes remain for alkaline batteries; the time remaining for nonalkaline batteries is not predictable.	Install new batteries.

Message or Condition	Cause	Recommendation
Unexpected result when power, backlight, or print button is pressed.	Debris (lint, etc.) is causing button to stick.	Disassemble the oximeter and remove debris from between the button cover and the circuit board.
	Damaged button cover.	Replace the button cover.
	Faulty circuit board.	Replace the circuit board.

Service policy

Warranty repair and service must be performed by Datex-Ohmeda. When the oximeter is out of warranty, repairs are made by Datex-Ohmeda at the current list price for replacement parts plus a reasonable labor charge.

Do not use malfunctioning equipment. Make all necessary repairs or have the oximeter repaired by a Datex-Ohmeda service representative. For all repairs, use only genuine replacement parts and service kits sold by Datex-Ohmeda.

CAUTION: Maintenance and repair. An operator may perform only maintenance procedures specifically described in this manual. Refer servicing to qualified service personnel who are trained in the repair of this equipment.

Ordering parts and obtaining service

Contact Datex-Ohmeda or your authorized service office (see the back cover of this manual) to order parts or for assistance.

Packaging and returning equipment

If you are instructed to ship the oximeter to Datex-Ohmeda or an authorized service office for repair, follow these steps:

1. Clean the oximeter. See *Cleaning the oximeter* earlier in this chapter. Make sure the oximeter is completely dry before you pack it for shipment.
2. Package the oximeter carefully for shipment (in the original shipping container, if possible).
3. You may be required to include the following items (when you call for assistance, verify the shipping requirements):
   - A letter describing the problem in detail.
   - Person (name, telephone or fax number, and country) to contact for questions about necessary repairs.
   - *Ship to* and *Bill to* information.
   - Warranty information (a copy of the invoice or other applicable documentation).
   - Purchase order number to cover repairs (if out of warranty) or for tracking purposes.
4. Ship the oximeter as directed by your service office.

Repair procedures

Follow the procedures in this section to inspect the oximeter for damage and replace damaged or defective parts.

WARNING: Electrical shock and flammability hazard. Power off the oximeter before cleaning or servicing.

CAUTION: Maintenance and repair.

- An operator may perform only maintenance procedures specifically described in this manual. Refer servicing to qualified service personnel who are trained in the repair of this equipment.
- Internal electronic components are susceptible to damage by electrostatic discharge. To avoid damage when disassembling the oximeter, observe the standard precautions and procedures for handling static-sensitive components.

Tools and equipment

- Phillips screwdriver (#1)
- Small, flat-blade screwdriver

Disassembling the oximeter

Important: As you disassemble the oximeter, carefully set aside each part you plan to reinstall when you assemble the oximeter.

Inspect the interior of the oximeter for damage or debris. Inspect all parts for damage. Remove debris and replace visibly damaged parts.

Note: All parts are shown in *Assembly drawing* later in this chapter.

1. Power off the oximeter and disconnect the sensor.
2. Turn the oximeter face down and loosen the screw that secures the battery door. Remove the door and the batteries.
3. Remove the 3 screws that secure the back case to the front case.
4. To separate the back case from the bumper, pull gently on the sensor connector and the battery door slots. When the bumper between the sensor connector and back case is loose, lift it slightly. Remove the sensor connector and back case from the bumper.
5. Grasp the edges of the circuit board. Slowly tilt it from side-to-side as you pull the back case away from the battery contacts. Do not bend or apply pressure to the battery contacts.
6. Grasp the sensor connector cable where it connects to the circuit board. Pull gently to disconnect the cable from the board.
7. Slide the bumper out of the front case slots. While removing the bumper, do not press against the lens (from inside or outside).
8. Lift the button cover from the small posts that secure it inside the front case.

Replacing parts

You can replace any part listed below with a new part as you assemble the oximeter:

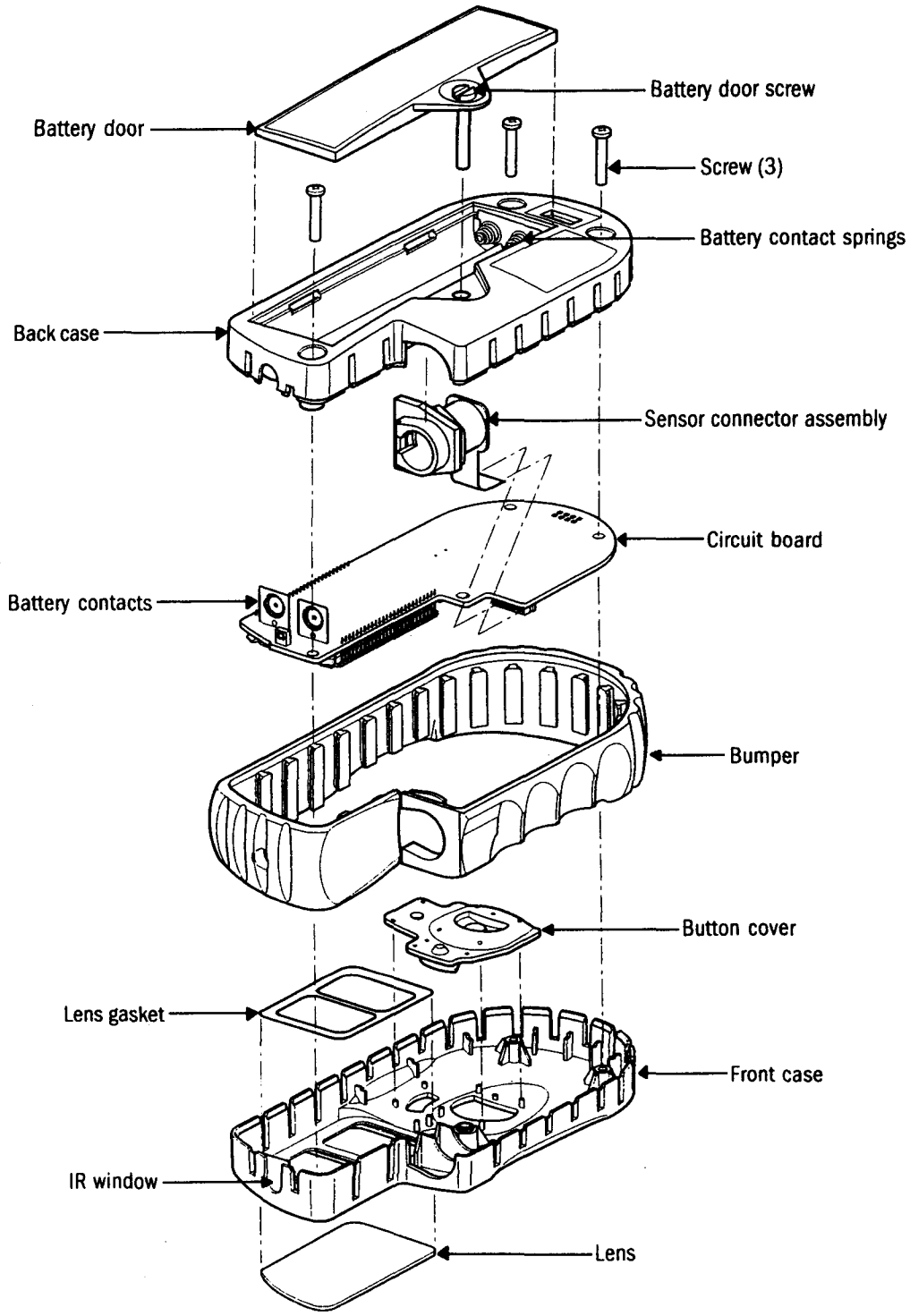
- Front case (with installed lens, lens gasket, and IR window)
- Button cover
- Bumper
- Sensor connector assembly
- Circuit board
- Back case (with blank label and installed battery contact springs).
- Battery door

Assembling the oximeter

1. Position the button cover over the small posts in the front case and press it into place.
2. Align the hole in the bumper with the IR window in the front case. Wrap the bumper around the case, aligning the slots. Slide the bumper onto the case.
3. Connect the sensor connector assembly cable to the circuit board:
   - Grasp the cable near its connector and align its connector with the connector on the circuit board.
   - Gently (but firmly) slide the cable into the circuit board connector until it is firmly seated.
4. Position the circuit board in the front case. Carefully bend the cable to position the sensor connector over its slot in the case. Slide it into the slot. Adjust the bumper around the sensor connector to ensure a snug fit.
5. Align the notches on the back case with the bumper. Be sure that the 2 battery contacts on the circuit board slip into the 2 slots in the battery compartment. Press down on the case, working your way around the unit.
6. When the back case is pressed firmly against the front case, install the 3 screws that secure the back case to the front case.

   Note: If you installed a new back case, remove the old label or write the information it contains on the blank label. Attach the label to the new back case.
7. Install the batteries and battery door:
   - Align the + on each battery with the + shown inside the battery compartment.
   - Position the battery door hinges in the slots on the back case, close the door, and tighten the screw that secures it to the unit.
8. Complete the *Checking normal operation* procedure in chapter 2.

Assembly drawing



Parts list

TuffSat Pulse Oximeter

TuffSat 6051 0000 148
TuffSat and FingerClip sensor, 0.91 m (3 ft.) 6051 0000 153

Miscellaneous

Carrying case, neoprene (standard) 6050 0005 554
Carrying case (deluxe) 6050 0005 653

TuffSat User's Guide and Service Manual

Danish 6050 0005 572
Dutch 6050 0005 574
English 6050 0005 576
Finnish 6050 0005 578
French 6050 0005 580
German 6050 0005 582
Italian 6050 0005 584
Japanese 6050 0005 586
Polish 6050 0005 664
Portuguese 6050 0005 588
Spanish 6050 0005 590
Swedish 6050 0005 592

Sensors

Refer to the sensor chart that accompanies this manual for a list of the sensors you can use with the TuffSat.

Service kits and parts

Refer to the *Assembly drawing* in this chapter.

Bumper 6029 0000 103
Button cover 6034 0000 012
Sensor connector assembly 6050 0005 566
Service kit, circuit board 6050 0005 643
Service kit, back case 6050 0005 644
Includes: Back case, blank label, and installed battery contact springs
Service kit, battery door/hardware 6050 0005 645
Includes: Battery door, battery door screw, and Phillips screws (3)
Service kit, front case 6050 0005 646
Includes: Front case with installed lens, lens gasket, and IR window

4/Compliance and Specifications

This chapter contains:

- Information about the tests that were conducted and the regulations with which the oximeter complies to assure its safe use.
- Performance specifications for the oximeter.

Electromagnetic compatibility (EMC)

The TuffSat pulse oximeter complies with the requirements of IEC/EN 60601-1-2 (1993): Electromagnetic compatibility - Requirements and tests.

Electromagnetic effects

Indications that the oximeter is experiencing electromagnetic interference include the following:

- Variations in the display (pleth bar does not correlate to physiological signals).
- Sudden increases or decreases in the pulse strength indicator that do not correlate to the physiological condition of the patient.
- Dashed messages that are not resolved by the instructions found in this manual when a valid physiological signal is present.

This interference may be intermittent and careful correlation between the effect and its possible source is important. The system will not display any of these effects if it is used within its intended electromagnetic environment.

EMC performance

The following EMC standards were applied to verify conformance of the oximeter.

Immunity: IEC/EN 61000-4-2 (1995), 8 kV, 3 kV contact
IEC/EN 61000-4-3 (1995), 3V/m
IEC/EN 61000-4-4 (1995), 500 V sensor cable

Emissions: IEC/EN 55011 Group I, Class B (1997)

The oximeter was tested at room temperature while operating on battery power using alkaline batteries.

Compliance with standards

The presence on the monitor of any symbol described below indicates compliance with the standard represented by that symbol.

CE 0197 Medical Device Directive 93/42/EEC of the European Union for a class I (with a measuring function), IIa, IIb, or III device.

LR 87853 c SP us Medical electrical equipment classified in the US and Canada with respect to electric shock, fire, and mechanical hazards only, in accordance with the Canadian Standards Association CAN/CSA C22.2 No. 601.1 (1990) and Underwriters Laboratories Inc. UL 2601-1 (1997).

General safety requirements

The oximeter complies with the requirements of IEC/EN 60601-1 (1988) Part 1: General requirements for safety of medical electrical equipment, including Amendment 1 (1991) and Amendment 2 (1995).

Type BF applied part.

Type of protection against electric shock: Internally powered equipment

Degree of protection against ingress of liquids: Ordinary (IPX0)

Mode of operation without exceeding temperature limits: Continuous

The oximeter also complies with the following:

EN 60601-1-1 (1993) Medical Electrical Equipment; Part 1: General requirements for safety – 1. Collateral standard: Safety requirements for medical electrical systems

Requirements for pulse oximeters

The oximeter complies with these specific requirements for pulse oximeters (as they apply to a device that has no alarms and is not intended for continuous monitoring):

ISO 9919 (1992) Pulse oximeters for medical use – Requirements

EN 865 (1997) Pulse oximeters – Particular requirements

Software safety checks

The Datex-Ohmeda software design controls include performance of a risk analysis using methods consistent with EN 1441 (1997 E) Medical devices – Risk analysis. The TuffSat oximeter employs a watchdog timer, self-monitoring activities (stack check, range check of inputs, etc.), and power-on self-tests (display checks and calibration verification). The software continuously monitors the sensor and, if a failure is detected, discontinues power to the sensor.

Performance specifications

Unless otherwise indicated, all specifications are nominal and are subject to change without notice.

General

Total operational time: approximately 17 to 20 hours at room temperature using alkaline batteries

Microprocessor-controlled device

Automatic self-test at power on

Automatic/continuous system diagnostics

SpO_2

Calibration: functional

Range: 0 to 100%

Accuracy (± 1 standard deviation):
80 to 100% ± 2%
60 to 79% ± 3%
Below 60% unspecified

First reading (full accuracy):
≤ 12 seconds from power on
≤ 10 seconds while oximeter is on

Interfering substances

Carboxyhemoglobin may erroneously increase readings in all pulse oximeters. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Cigarette smokers and victims of smoke inhalation often have increased levels of carboxyhemoglobin. Dyes that change usual arterial pigmentation, or substances containing dyes, may also cause erroneous readings.

Sensor emitter wavelength ranges

Red LED peak wavelength range: 650 to 665 nm

Infrared (IR) LED peak wavelength range: 930 to 950 nm

Average power: ≤ 1 mW

Pulse rate

Range: 40 to 255 beats per minute (bpm)

Accuracy, assuming a constant pulse rate (± 1 standard deviation):
40 to 100: ± 2 bpm
100 to 255: ± 2%

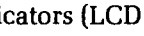
First reading (accuracy reduced ± 5 bpm for ≤ 17 seconds, then full accuracy):
≤ 12 seconds from power on
≤ 10 seconds when oximeter is on

Alarms

No alarms (audible or visual) for any situation, including low SpO_2 and high/low pulse rate

Displays

SpO_2 and pulse rate liquid crystal display (LCD)

Indicators (LCD icons): low battery  and print

Backlight: edge-lit yellow light-emitting diode (LED)

Pleth bar (pulse rate signal strength): a column of eight segments (8 LCD icons); during monitoring, the lowest segment is always on

Updates

The displayed SpO_2 and pulse rate values are updated every second. The pleth bar is updated continuously.

Visibility

Visibility without backlight: visible in normal light (fluorescent, 215 Lux) from 1.5 meters (5 feet) at 30° angle from above and 45° angle from the left, right, and below

Visibility with backlight: visible in dark room from 0.6 meters (2 feet) at 30° angle

Power

Four 1.5V AA batteries (alkaline, rechargeable alkaline, NiCad, carbon, lithium, etc.)

Low battery indicator (screen icon)

Flashes on/off when battery power is low and fresh batteries are needed. The icon continues to flash on/off until (1) the batteries are replaced, (2) no power is left to power the oximeter, or (3) the oximeter is powered off.

The first time the icon flashes on/off, 10 to 60 minutes of battery life remains for alkaline batteries when the oximeter has been operated at room temperature. The time remaining for nonalkaline batteries is not predictable–the battery type determines the capacity, operation time, and life cycle of the battery.

Environment

Parameter	Operating	Transport and Storage
Temperature	-10 to 60 °C (14 to 140 °F)	-40 to 70 °C (-40 to 158 °F)
Humidity	10% to 95% RH noncondensing	5% to 95% RH noncondensing
Altitude	700 to 1060 hPa -378 to 3048 m (-1240 to 10,000 ft.)	120 to 1060 hPa -378 m to 15 km (-1240 to 50,000 ft.)

Dimensions and weight

15 cm (6 in.) x 7 cm (2.8 in.) x 3 cm (1.2 in.)

Weight (with four 1.5V AA alkaline batteries): 257 g (9 oz.)

Appendix: Printer Features and Use

This chapter contains:

- Information about how the TuffSat pulse oximeter stores data for printing to the optional Hewlett-Packard infrared printer and descriptions of the printer's components.
- Instructions for using the printer.
- Sample printouts.
- A chart for troubleshooting situations that may occur while using the printer.
- Instructions for replacing the paper roll and cleaning the printer.
- Order numbers for the printer and printer accessories.
- Performance specifications for the printer.

Functions and features

You can use the optional Hewlett-Packard infrared printer (HP 82240B) with the TuffSat pulse oximeter to do the following:

- Print real-time data while monitoring a patient (the printout is for archival or record-keeping purposes only).
- Print stored trend data after monitoring one or more patients.

How the TuffSat oximeter stores data

The TuffSat automatically stores SpO_2 and pulse rate trend data starting 15 seconds after you begin monitoring a patient, then every 2 minutes. The oximeter can store up to 32 data points (approximately 64 minutes of monitoring data). When the stored trend data exceed 32 data points, the oldest data are overwritten.

The oximeter can store trend data for up to 32 patients, provided it remains powered on between patients. The oximeter identifies a new patient and appends new monitoring data to stored data when you do the following:

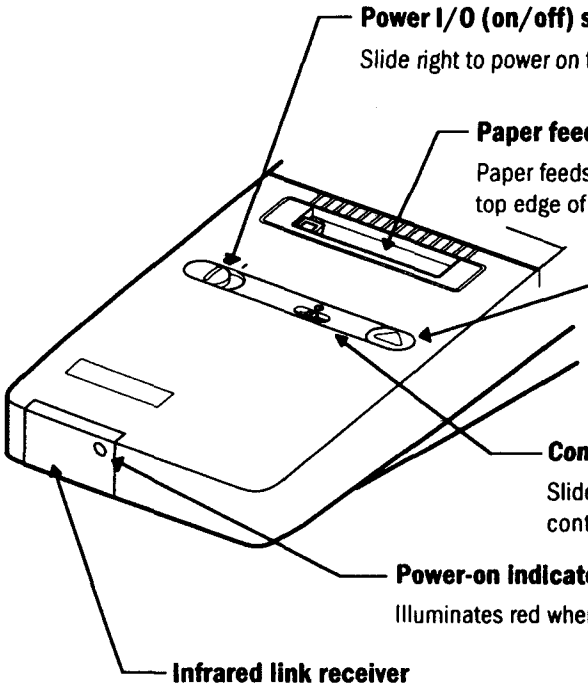
- Remove the sensor (stop monitoring) for at least 15 seconds.

  and

- Start monitoring the new patient within 5 minutes.

Important: The TuffSat stores data only while the power is on.

Printer components


Power I/O (on/off) switch
Slide right to power on the printer; slide left to power it off.
Paper feed slot
Paper feeds out from the printer through this slot. Use the top edge of the plastic slot cover to tear off the paper.
Paper advance button
Press to feed paper from the roll through the slot and to advance the paper when printing is complete.
Contrast selector
Slide left for low contrast; slide right for high contrast.
Power-on indicator
Illuminates red when the printer is on.
Infrared link receiver
Receives data to be printed from the oximeter's infrared link transmitter.

Using the printer

Powering the printer

WARNING: Fire/explosion hazard. Do not use the printer in the presence of a flammable anesthetic mixture with air, or with oxygen or nitrous oxide.

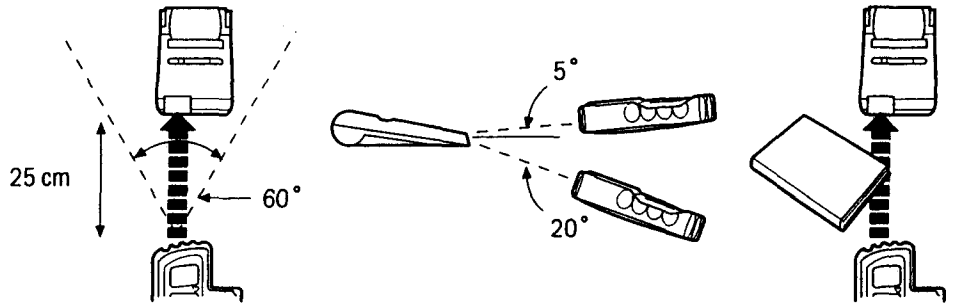
CAUTION: To avoid damage to the printer, use only an AC adapter recommended by and available from Datex-Ohmeda.

CAUTION: Connect the adapter to a proper power source according to the voltage and grounding requirements found on the product case. Unplug it from the power source when it is not in use.

1. Before you begin, check the following:
   - The printer has paper.
   - Four 1.5V alkaline AA batteries are installed in the printer.
2. If you are using the AC adapter, verify that it is the correct adapter for your local line voltage. Then, connect the adapter:
   - Plug the AC adapter into the port on the back of the printer (left of the paper roll door).
   - Connect the adapter to the AC mains power supply.
3. To power on the printer, move the I/O slider to the right–the I (on) position.

Positioning the oximeter and printer

To prevent data loss or incorrect characters on the printout, position the infrared transmitter on the oximeter and the infrared receiver on the printer in relation to each other as shown below.



Transmitting distance and angle | **Vertical positioning** | **Do not block infrared link**

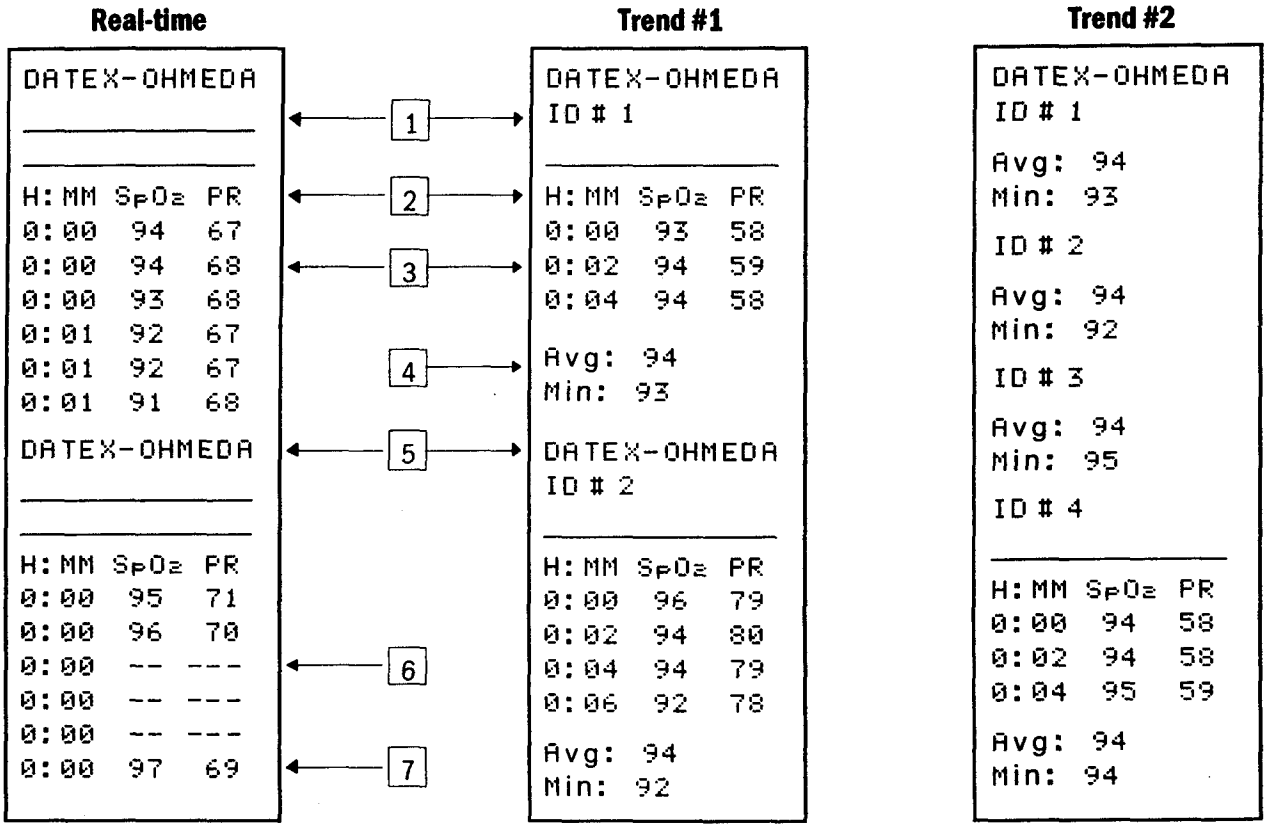
Printing data

When the printer is on and correctly positioned with the oximeter, you are ready to print.

1. On the oximeter, press the button to start printing.
   - *Real-time data* print if you are monitoring a patient (a sensor is on the patient and is connected to the oximeter).
   - *Stored trend data* print if you are not monitoring a patient.
2. Do not move the oximeter or printer until printing stops.
3. To stop printing, press the print button.
4. When printing stops, press to advance the paper.

Important: To avoid a paper jam, tear the paper off *after* the print head stops moving and *after* the paper stops advancing.

Sample printouts



Real-time printout *and* Trend #1 printout

1. Both printouts contain lines for adding comments. The trend printout contains a patient identification number (ID#).
2. H:MM indicates the elapsed time since monitoring began for the patient in hours (H) and minutes (MM).
3. *Real-time:* SpO_2 and pulse rate (PR) values print every 15 seconds.

   Trend: The first data point was stored 15 seconds after monitoring began, then every 2 minutes.
4. The average (Avg) and minimum (Min) SpO_2 data points for each patient.
5. *Real-time:* A new heading prints if you stop, then restart printing.

   Trend: A new ID# indicates monitoring stopped for at least 15 seconds.
6. Dashes (---) indicate the finger was removed from the sensor while printing.
7. Monitoring resumed–the sensor was placed on the same patient or on a different patient while printing.

Trend #2 printout

When the monitoring data exceed 32 data points, the oldest data are overwritten. However, the TuffSat oximeter reports the patient ID number, average SpO_2, and minimum SpO_2 for up to 100 patients whose data were overwritten.

Troubleshooting

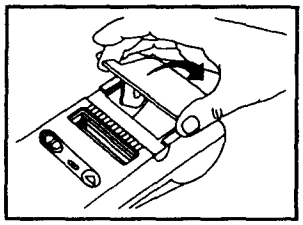
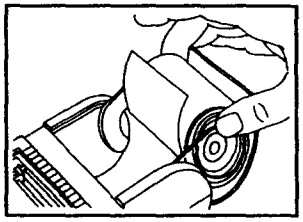
This chart lists conditions you may encounter while using the printer, possible cause(s), and recommendations for correcting the condition.

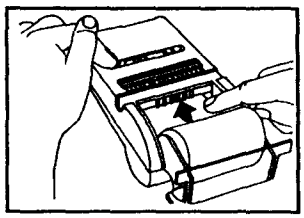
Message or Condition	Cause	Recommendation
Printer won't print.	No data in the trend buffer.	No action required.
	Printer batteries are dead or not installed, the AC adapter is not connected, or the printer is not on.	Install batteries, check the AC adapter connections, and/or turn on the printer. See *Powering the printer.*
	Printer is not receiving transmission from the oximeter due to improper positioning.	Reposition the printer and oximeter for infrared transmission. See *Positioning the oximeter and printer.*
	Printer or oximeter component malfunction.	Replace the printer. If the condition persists, replace the A/D board.
■ is printed.	Printer is too close to oximeter or too low.	Move the printer farther away or raise it slightly. See *Positioning the oximeter and printer.*
	Infrared beam is blocked.	Remove the obstruction.
	Interference from another infrared source.	Remove the other infrared source. Check the AC adapter connection.
▨ is printed.	The printer cannot print fast enough to keep up with incoming data.	Install new printer batteries. Use AC power if possible.
Printer prints repeatedly over a single line.	Paper jam.	Pull paper out and reload. See *Replacing printer paper.*
Print head does not move.	Printer malfunction.	Replace the printer.

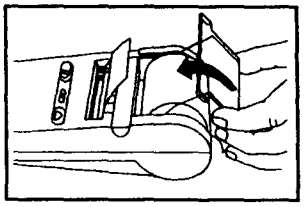
Printer maintenance

Replacing printer paper

To assure proper operation of the printer, be sure paper is installed before you try to print. Use only paper rolls supplied by Datex-Ohmeda.

1. Press (△) to advance the remaining paper through the mechanism.
   - Never pull the paper backward or forward through the printer mechanism.
   - If the paper is attached to the inner core, do not run the paper through to the end of the roll. (Datex-Ohmeda paper is not attached.)
2. Tear or cut the end of the paper evenly. Do not use paper with folds or uneven edges.
3.  Open the paper roll door and remove the used paper roll core.
4.  Position the new paper roll in the door.
   Note: The paper spools from the bottom of the roll.

   Verify that the printer mechanism is not obstructed.
5.  Hold down the (△) button and gently push the paper into the slot. When the paper emerges, release the button.

   If the paper jams, pull it back slightly–just enough to free the jammed paper.
6.  Place the paper roll in the compartment and close the door.

Cleaning the printer

WARNING: Electrical shock and flammability hazard. Before cleaning the printer, turn it off and disconnect it from AC mains power.

CAUTION: Follow these guidelines when cleaning the printer:

- Do not autoclave, pressure sterilize, or gas sterilize the printer.
- Use cleaning solutions sparingly. Do not immerse the printer in liquid. Excessive solution may flow into the printer and damage internal components.
- Do not use petroleum-based solutions or solutions containing acetone, freon, or harsh solvents. These substances may damage the printer and cause a malfunction.

1. Power off the printer and disconnect it from AC mains power.
2. Moisten a lint-free cloth with water or a mild cleaning solution, such as 70% isopropyl alcohol, and wipe the surface of the printer.
3. Allow the printer to dry thoroughly.

Ordering the printer and printer accessories

The HP® printer is not a serviceable part. Replace the printer when it fails to function as specified.

CAUTION: Disposal. When the printer has reached the end of its useful life, dispose of it in accordance with local procedures and regulations.

Hewlett-Packard infrared printer (HP 82240B) 6002 0000 084

Paper rolls (6/package) 6050 0003 058

Printer AC adapter

USA/Canada/Latin America (120 V 60 Hz) 6051 0000 066

Elsewhere (220 – 240 V 50 Hz) 6051 0000 081

Printer specifications

Electromagnetic compatibility (EMC)

The HP printer is suitable for use in the EM environment described in IEC/EN 60601-1-2 with the limitations noted below.

- When the printer is experiencing electromagnetic interference, extra print characters, spaces, or black boxes may be inserted in the printout. The printer is not damaged and normal operation is restored when the source of interference is removed.
- Printer disruptions do not affect the oximeter or trend data stored in memory.

The printer will not print correctly under the most severe test levels of IEC/EN 61000-4-2 and 61000-4-4, however, no permanent damage occurs.

Print indicator (screen icon)

Appears on the screen while printing.

Power

AC adapter (with four 1.5 V AA batteries in printer)

Voltage: 9 to 12 V (ac or dc)

Current: 500 to 1500 mAmps

Environment

Parameter	Operating	Storage
Temperature	0 to 50 °C (32 to 122 °F)	-40 to 60 °C (-40 to 140 °F)
Humidity	15 to 95% RH at 40 °C (104 °F)	Paper: 50 to 90% RH Printer: 5 to 95% RH
Atmospheric pressure	700 to 1060 hPa (8 to 16 psia)	500 to 1060 hPa (7.25 to 16 psia)

Dimensions

18.5 cm (7.3 in.) x 9 cm (3.5 in.) x 2.5 to 6 cm (1 to 2.4 in.)

Weight: 0.45 kg (1 lb.) with paper and batteries

Warranty

The TuffSat™ Pulse Oximeter (the product) is sold by Datex-Ohmeda, Inc. only under the warranties set forth in the following paragraphs. Such warranties are extended only with respect to the purchase of the product directly from Datex-Ohmeda Authorized Dealers as new merchandise and are extended to the first Buyer thereof, other than for resale.

Limited warranty

Datex-Ohmeda warrants that the product meets the published specifications at the time of shipment from the factory.

Products not under warranty

The following items are not covered under this warranty: disposable items, accessories, service kits, and replacement parts. These items may be covered under a separate warranty. Consult Datex-Ohmeda for details.

Duration

The product is warranted against defects in materials and workmanship for a period of three (3) years from the date of delivery to the user (in no event for a period of more than four [4] years from the date of original delivery by Datex-Ohmeda to an Authorized Dealer).

If any part of the product proves defective under proper and normal use within the warranty period, as the purchaser's exclusive remedy, Datex-Ohmeda will repair or replace, at its sole discretion, the product or any defective part provided it is returned to Datex-Ohmeda Service within 30 days of the failure.

Limitation

Datex-Ohmeda may at any time discharge its warranty obligation by repairing and returning the product to original factory performance. This may be accomplished by installing new or remanufactured assemblies or by other repairs deemed appropriate by Datex-Ohmeda. The choice of repair or replacement by Datex-Ohmeda shall be the sole remedy of the buyer or user.

Conditions

This warranty is valid only when qualified personnel have performed installation and service on the product and when all recommended planned maintenance procedures have been completed during the warranty period. Damage caused by the abuse or misuse of the product is not covered by this warranty. Datex-Ohmeda shall not be liable for damage resulting from the improper installation or the misuse of the product.

Exclusion of warranties

Oral statements about the product do not constitute warranties, shall not be relied on by the buyer or user, and are not part of any warranty extended by Datex-Ohmeda.

Except as set forth in this limited warranty, Datex-Ohmeda makes no warranties, expressed or implied, including the implied warranty of merchantability and the implied warranty of fitness for a particular purpose. Except for the obligations under this limited warranty, Datex-Ohmeda shall not have any obligation or liability for any incidental or consequential damages (including those from commercial loss) or other loss, damage, or injury resulting directly or indirectly from the product.

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